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No. 03-2

In the Supreme Court of the United States

OXFORD ASSET MANAGEMENT, LTD.,
and SUSMAN & WATKINS,
Petitioners,

v.

MICHAEL JAHARIS, *et al.*,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Eleventh Circuit

BRIEF FOR UNDERWRITER RESPONDENTS IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether a complaint may be dismissed under Rule 8 of the Federal Rules of Civil Procedure on the ground that it pleads only conclusions that are based on unwarranted deductions of facts or that are contradicted by the documents attached to or relied upon in the complaint.

2. Whether Section 11 of the Securities Act of 1933 should be interpreted in accordance with its plain terms to give rise to a cause of action based on an allegedly material omission only when the omitted facts (a) were required to be disclosed in the registration statement by SEC regulations or (b) were necessary to make what was actually said in the registration statement not misleading.

3. Whether it is an abuse of discretion for a district court to sanction a plaintiff and its counsel in a case brought under Section 11 based on its conclusion that the allegations of material misrepresentations in the complaint were "objectively frivolous."

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Respondent SG Cowen Securities Corp. is wholly owned by SG Americas, Inc. SG Americas, Inc. is wholly owned by Societe Generale, which is a publicly traded company. No other publicly-held company owns 10% or more of respondent SG Cowen Securities Corp.'s stock.

Respondent Salomon Smith Barney Holdings, Inc. is now known as Citigroup Global Markets Holdings Inc. Citigroup Global Markets Holdings Inc. is wholly owned by Citigroup Inc., which is a publicly traded company. No other publicly-held company owns 10% or more of respondent Salomon Smith Barney Holdings, Inc.'s stock.

Respondent Warburg Dillon Read, L.L.C. is now known as UBS Securities LLC. UBS Securities LLC is wholly owned, directly and indirectly, by UBS AG, which is a publicly traded company. No other publicly-held company owns 10% or more of respondent Warburg Dillon Read, L.L.C.'s stock.

Respondent Donaldson, Lufkin & Jenrette is now known as Credit Suisse First Boston LLC. Credit Suisse First Boston LLC is wholly owned by Credit Suisse First Boston (USA), Inc. Credit Suisse First Boston (USA), Inc. is indirectly owned by Credit Suisse Group, which is a publicly traded company. No other publicly-held company owns 10% or more of respondent Donaldson, Lufkin & Jenrette's stock.

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BRIEF FOR UNDERWRITER RESPONDENTS IN OPPOSITION

This brief is submitted by the underwriters who were named as defendants in the Section 11 and Section 12(a)(2) claims brought by plaintiff-petitioner Oxford Asset Management, Ltd.: SG Cowen Securities Corp., Donaldson Lufkin & Jenrette, Salomon Smith Barney Holdings, Inc., and Warburg Dillon Read, L.L.C. (referred to collectively herein as the "Underwriter Respondents").

STATEMENT

Petitioners' Statement contains a number of misstatements of fact — about what was said in the Prospectus at issue here, about what was pleaded in petitioners' own complaint, and about the basis of the Eleventh Circuit's decision affirming the dismissal of the complaint and the imposition of sanctions. When those misstatements are stripped away, it becomes apparent that there is nothing in the decision below that warrants review by this Court.

A. The Prospectus.

Kos Pharmaceuticals, Inc. ("Kos") was founded in 1988 to develop and commercialize prescription drugs for the treatment of certain chronic cardiovascular and respiratory diseases. Prospectus, Ex. A to Complaint, C.A. App. D, at 3-4. The Company successfully completed an initial public offering of stock in March 1997, before it had received FDA approval to market any drug. *Id.* at 18. On July 28, 1997, the Company was granted clearance by the FDA to market its first drug, Niaspan®. *Id.* at 3. On October 24, 1997, Kos and two of its founding shareholders completed a second public offering of Kos stock underwritten by the Underwriter Respondents. Complt. ¶ 2. It is the prospectus for that public offering (the "Prospectus") that is at issue in this case.

Niaspan® is a once-a-day, controlled release formulation of niacin, which is a water soluble vitamin. Prospectus at 22. Niacin has long been recognized as an effective agent in reducing "bad" cholesterol and increasing "good" cholesterol in patients with heart disease. *Id.* at 23. However, niacin's adverse side effects prevented it from becoming widely accepted. Niacin frequently caused patients to suffer intolerable "flushing," in the form of facial redness and tingling, often accompanied by a rash. *Id.* at 24. Niacin also was associated with a high incidence of liver toxicity. *Ibid.* Niaspan® was designed to minimize these side effects, while at the same time effectively treating patients' cholesterol problems. *Id.* at 23, 24.

The Prospectus summarized the test data concerning efficacy, safety and tolerability that the Company had submitted to the FDA to obtain approval for Niaspan®. Among other things, the Prospectus reported study results showing that patients taking Niaspan® experienced a significantly lower incidence of the side effects that previously had prevented widespread acceptance of niacin. Nevertheless, the Prospectus warned investors that patients' actual experience with Niaspan® could differ from the test results and that there was a risk that doctors who had had bad experiences with niacin in the past might be reluctant to prescribe Niaspan®:

> The Company believes that intolerable flushing is a principal reason why physicians generally have been reluctant to prescribe or recommend currently available formulations of niacin. . . . Although most patients taking Niaspan® will sometimes flush, the formulation and dosing regimen for Niaspan® have been designed to maximize patient acceptance and minimize the occurrence of flushing. *There can be no assurance, however, that patients using Niaspan® will not suffer episodes of flushing that they consider intolerable. The failure of physicians*

> *to prescribe Niaspan® or the failure of patients to continue taking Niaspan® due to intolerable flushing or to other side effects would have a material adverse effect on the Company.* The Company believes that physicians have also been reluctant to prescribe or recommend certain currently available formulations of niacin because of potential liver toxicity associated with these formulations. Although clinical trials conducted using Niaspan® demonstrated that fewer than 1% of patients experienced clinically significant elevations in liver enzyme levels, *there can be no assurance that patients using Niaspan® in actual practice will not experience clinically significant elevations of liver enzymes or other side effects at a rate higher than those experienced in the Company's clinical trials.*

Prospectus at 6 (emphasis added).

The Prospectus also warned that Kos' "marketing experience to date is limited," that the Company had a smaller sales force than its competitors, and that there could be no assurance that its sales force would be able to successfully market the product to physicians who prescribe lipid-altering medications. Prospectus at 8-9. The Prospectus noted that there were many commercially available products for the treatment of elevated LDL cholesterol (and others under development) and that the manufacturers of those products had greater financial resources, sales, and manufacturing capabilities than Kos. *Id.* at 9. Thus, even if Niaspan® turned out to be a superior product, the Prospectus warned that other entities might be more successful in marketing their competing products. *Ibid.*

The Prospectus did not contain any optimistic predictions about likely future sales of Niaspan®. On the contrary, it

warned that sales of Niaspan® were likely to get off to a slow start. The Prospectus explained that the Company's strategy was to provide complimentary three-week starter packs of Niaspan® for physicians to give their patients, in the hope that the physicians would then begin to write prescriptions for Niaspan®. Because of the significant marketing challenges confronting the Company and the three-week trial offer, the Prospectus cautioned investors that it was likely that, after the initial product launch, prescription sales of Niaspan® would increase only "modestly":

> As part of the Company's detailing effort, three-week Niaspan® titration starter packs are given to physicians as a promotional item to start their patients on Niaspan®. These titration packs generally are dispensed without a prescription. Further, physicians being detailed by the Company may have had unsatisfactory experiences with currently available generic formulations of niacin, the active ingredient in Niaspan®. The Company believes, therefore, that during the initial months following the launch of Niaspan®, many physicians may start only a limited number of selected patients on Niaspan® in order to confirm its efficacy, safety, and tolerability. Consequently the Company believes that during this three-to-six month period, prescriptions for Niaspan® are likely to increase modestly.

Prospectus at 25-26.

Contrary to the assertion in the petition (at 4), the Prospectus did *not* contain any estimate of future earnings — let alone an estimate based on the assumption that 5000 prescriptions would be written within the first eight weeks after Niaspan® was launched. In fact, the Prospectus made it clear that Kos had consistently lost money while it was in its development stage (reporting losses of $11, $21 and $23

million in 1995, 1996 and 1997, respectively) and that it expected to continue sustaining significant losses for at least six months and possibly longer after the marketing of Niaspan® had begun:

> The Company expects to incur significant operating losses for at least the next six months, primarily due to continued investments in its research and development programs and for manufacturing and marketing, sales and administrative expenses associated with the launch of Niaspan®. *No assurance can be given that additional significant losses will not continue thereafter.*

Prospectus at 6 (emphasis added).

Although Kos did not make any earnings estimate in the Prospectus, the market was no doubt aware of a revenue forecast that was independently made by Robert Uhl, who was an analyst for Salomon Smith Barney. Before the launch, Mr. Uhl predicted that Niaspan® sales would be $12 million for 1997 and $92 million for 1998. C.A. App. F, at 2. However, the Prospectus did not even mention — let alone purport to endorse — Mr. Uhl's prediction. Indeed, the information in the Prospectus made it clear that Kos had a long way to go to achieve the level of sales Mr. Uhl had predicted. For the quarter ending September 30, 1997, which included the first six weeks Niaspan® had been on the market, the Prospectus estimated that Kos had achieved revenues of only $1.5 million as a result of sales of Niaspan® to wholesalers — leaving it $10.5 million shy of Mr. Uhl's predicted revenue target, with only one quarter left to go. Prospectus at 18.[1]

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[1] Under SEC Regulations, the Prospectus was not required to include this kind of quarterly financial information. Because Kos included in the Prospectus its audited financial statements as of the

The public offering closed on October 21, 1997. Approximately three weeks later, on November 12, 1997, Mr. Uhl issued another report in which he cut in half his revenue predictions for sales of Niaspan® for the remainder of 1997 through 2000 and downgraded Kos' stock from a "buy" to a "hold." The petition states that Mr. Uhl revised his previous prediction based on "the first eight weeks of prescription data," which is "generally considered to be a reliable indicator of future commercial performance." Pet. 4. But, as the Uhl report, the complaint, and the opinions below all make clear, Mr. Uhl's prediction was based not on eight weeks' worth of prescription data, but rather on data concerning the level of sales in the *eighth week* after Niaspan® went on the market. C.A. App. F, at 2-3, Pet. App. 3, 51. It is undisputed that the eighth week ended on October 31, 1999 — ten days *after* the public offering was completed. Pet. 4.

Significantly, nowhere in his November 1997 report did Mr. Uhl suggest that there was any problem with Niaspan® from the standpoint of safety or effectiveness; nor did he question the commercial viability of the drug. On the contrary, Mr. Uhl stated that "[e]ventually we are confident that Niaspan® will find its place in the market, but it appears that the initial acceptance will take longer and be slower than [we] originally expected."[2] C.A. App. F, at 4.

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close of its fiscal year on June 30, 1997, it could have avoided any disclosure of its relatively meager sales to wholesalers through the end of September. See Regulation S-X, Rule 3-12, 17 CFR § 210.3-12 (updated financial statements are required only if the company's annual financial statements are more than 135 days old). By voluntarily including this information in the Prospectus, Kos conveyed yet another cautionary message to potential investors.

[2] Echoing some of the risk factors outlined in the Prospectus, Mr. Uhl attributed some of the slowness in the growth of prescriptions to

Following the issuance of Mr. Uhl's revised recommendation, the market price of Kos stock fell sharply, prompting this lawsuit.

B. Proceedings Below.

On August 10, 1998, plaintiff filed this lawsuit, alleging that the Prospectus was materially misleading in a number of respects in violation of Sections 11 and 12(a)(2) of the Securities Act of 1933 and Section 10(b) of the Securities Exchange Act of 1934. Plaintiff sought damages against the Company, its officers and directors, and the underwriters of the offering on behalf of a purported class of purchasers of Kos stock under both state and federal law. Plaintiff did not accuse the Underwriter Respondents of engaging in deliberate fraud; instead, the only federal claims asserted against the Underwriter Respondents were claims under Sections 11 and 12(a)(2).

Throughout the proceedings in the lower courts, petitioners continually changed the theories they offered in support of their claim that the Prospectus was materially false or misleading. In fact, it was not until oral argument on the motion to dismiss that petitioners first raised the theory that was the centerpiece of their appeal to the Eleventh Circuit — that the defendants had violated a claimed duty to disclose information about the first six weeks' worth of prescription sales of Niaspan®. See Pet. App. 49 & n.21. Although the district court recognized that this claim was untimely, it nevertheless chose to review its sufficiency "in the interests of justice." *Ibid.*

In their petition, petitioners continue to focus on their omission claim as well as on two claims aimed at allegedly

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Kos' "relatively small" sales force, as well as to a lag in filling prescriptions that was produced by Kos' program of providing free three-week samples to physicians. C.A. App. F, at 2.

false or misleading statements in the Prospectus — all of which the lower courts found to be insufficient as a matter of law.

1. At page 5 of their petition, petitioners assert that prescription information from the first six weeks' worth of Niaspan® sales should have been disclosed in the Prospectus because it would have shown "that the level of Niaspan prescriptions could not support the prospectus' earnings estimates." This description, however, misstates petitioners' own claim. The Prospectus did not include any earnings estimates. Accordingly, petitioners never argued in the lower courts that prescription sales data was necessary to counterbalance such estimates.

Instead, petitioners' argument was that even a few weeks' worth of prescription information would have been material to a reasonable investor because it was information about weak prescription sales that caused the market price of Kos stock to drop sharply after the offering was completed. The district court rejected this argument. It noted that the "materiality of this information is highly questionable, if not absent" in light of the many cautionary statements in the Prospectus about the considerable risks Kos faced in marketing Niaspan®. Pet. App. 51. Moreover, the "relevant week . . . the analyst considered it reasonable to rely on" in changing his prediction of Kos' future revenues — the eighth week of sales — had "not even occurred when the Prospectus was filed and the Offering held." *Ibid.*

On appeal, the Eleventh Circuit affirmed. Although it recognized that the materiality of the information was marginal at best, the court assumed for purposes of argument that whatever information Kos may have had about prescription sales would have been material to a reasonable investor. The court nevertheless concluded that there was no duty to disclose the information because SEC regulations did not require this kind of data to be disclosed and because the failure to disclose

it did not render any statement that was made in the Prospectus materially misleading. Pet. App.12-16. The court rejected petitioners' argument that Section 11 imposes a general duty to disclose *all* material information in a registration statement, citing the plain language of Section 11, which creates a right of action for an omission in a registration statement only if it "omit[s] to state a material fact required to be stated therein or necessary to make the statements therein not misleading." *Id.* at 11-12.

2. Petitioners' second claim is that the Prospectus misrepresented Niaspan®'s efficacy by stating that it could boost "good" HDL cholesterol "by up to 32%." In the complaint, petitioners explained why they believed this statement was false, pointing to the fact that a July 1997 Kos press release and a 1996 article discussing a clinical trial of Niaspan® revealed an upper range of results that was lower than 32%.

In concluding that the complaint failed to state a claim for falsity on this point, the district court noted that there was nothing in the prior press release or article that contradicted the 32% claim in the Prospectus: the results reported in Kos' prior statements fell within the range of results reported in the Prospectus. Pet. App. 43. Moreover, both the Prospectus and the FDA-approved package insert for Niaspan® made it clear that they included new test results from *additional* studies that had not been reported either in the July 1997 press release or the 1996 article. *Ibid.*[3] At oral argument on the motion to

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[3] As defendants pointed out in the court below, the FDA-approved package insert contains a table that shows a mean increase in HDL of 32% — exactly the figure reported in the Prospectus as the high end of the range of mean increases reported in the various tests. C.A. R. 77, at 11. In this Court, petitioners do not challenge the propriety of the district court's decision to take judicial notice of the package

dismiss, plaintiffs' counsel acknowledged that the existence of these additional studies might well explain the differences between the Prospectus and Kos' earlier statements, stating that "it was 'very possible' that Defendants are 'right' about these figures." Pet. App. 43. The district court was unimpressed by petitioners' argument that they nevertheless were entitled to discovery because the truth of the statements made in the Prospectus "could not be confirmed" without a review of the additional studies. *Ibid.* The district court held, and the court of appeals agreed, that even under Rule 8's notice pleading requirements, a mere "suspicion (or less)" that plaintiffs "might have a basis for a claim" was not enough to avoid a motion to dismiss. *Ibid.*

3. Petitioners describe their third claim as alleging that the Prospectus was materially misleading because it failed to disclose that Niaspan® was supposedly "intolerable" at the effective dose of 2000 mg and because Kos allegedly based its "safety claims on defective clinical trials that excluded pre-menopausal women, who have lower tolerances to the drug's side effects." Pet. 6. This was not the claim that petitioners asserted in their complaint and litigated in the district court, however. Instead, the complaint alleged that only a "tiny fraction" of the potential market for Niaspan® could tolerate its side effects and that the studies described in the Prospectus, which indicated that a 2000 mg dose was in fact tolerable, "were 'rigged' to include only those individuals who had an unusually high tolerance." Pet. App. 46. Petitioners never suggested in their complaint or their arguments on the motion to dismiss that the studies in question were "rigged" because they improperly excluded pre-menopausal women. On the contrary, as the district court noted, plaintiffs' counsel was

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insert and other documents cited in the complaint. *See* Pet. App. 7-8, 39.

unable to offer any explanation as to why he thought the tests showing that a 2000 mg dose was tolerable were "rigged" other than to say that "there has to be some reason 'why physicians don't prescribe it.'" Pet. App. 47.[4]

The district court concluded that this claim also failed as a matter of law because plaintiffs had admitted that they had no factual basis for believing that any of the clinical tests described in the Prospectus had been "rigged." Because the test data, which had been presented to and relied upon by the FDA when it approved Niaspan®, contradicted plaintiffs' claim that only a "tiny fraction" of the population could tolerate a 2000 mg dose, the court concluded that the complaint failed to properly plead falsity on this theory as well. On appeal, the Eleventh Circuit agreed with this analysis. Pet. App. 19.

Contrary to the characterization in the petition, neither the district court nor the Eleventh Circuit purported to be applying a heightened pleading standard to plaintiffs' 1933 Act claims. Nor did they suggest that the Private Securities Litigation Reform Act ("PSLRA") had somehow altered the pleading standards for a motion to dismiss a 1933 Act claim. Instead, both courts explicitly stated that they were granting the defendants' motions to dismiss for failure to state a claim under Rule 8. Pet. App. 7, 35-37.

After their motions to dismiss were granted, the defendants filed motions for sanctions under Rule 11. After briefing and argument, the district court granted those motions, on the ground that plaintiffs should have realized, once they had completed their pre-filing investigation, that they had no factual basis for bringing any of the claims alleged in their complaint.

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[4] It was not until the defendants filed a motion for sanctions that plaintiffs first advanced the claim that the studies were "rigged" because they excluded pre-menopausal women.

The district court held that the claims asserted in the complaint were "objectively frivolous" and that petitioners had "demonstrated a deliberate indifference to their lack of factual support." Pet. App. 68. On appeal, the Eleventh Circuit largely agreed, holding that the only claim for which petitioners had any factual support – and the only one that was therefore not sanctionable – was the claim that the Prospectus should have included preliminary prescription data. Pet. App. 22.

REASONS FOR DENYING THE PETITION

The petition should be denied because the circuit conflicts petitioners rely upon either do not exist or are not implicated by the decision in this case. *First*, contrary to petitioners' argument, the courts below did not purport to apply or in fact apply a heightened pleading standard to petitioners' 1933 Act claims. Instead, the lower courts simply applied well-settled pleading rules to the specific facts alleged in this case. As a result, there is no conflict between the decision in this case and decisions in other circuits on the question of whether 1933 Act claims that "sound in fraud" should be subject to the heightened pleading requirements of Rule 9(b). Nor is there any issue of general importance for this Court to consider. Whether the lower courts' analysis of the specific allegations of the complaint was correct is an utterly fact-bound issue that plainly does not warrant this Court's review.

Second, the Eleventh Circuit's conclusion that there was no duty to disclose prescription information even if that information were deemed to be material does not create a conflict with the Second Circuit, as petitioners contend. Nor is it based on an erroneous construction of Section 11. The Eleventh Circuit read Section 11 just as it is written, to prohibit omissions of material facts that are either "required to be stated" in the registration statement or are "necessary to make the statements" that were made in that document "not

misleading." Petitioners do not challenge the court of appeals' conclusion that defendants were not required to disclose the prescription data by any SEC regulations. Nor do they contend that the court below erred in concluding that disclosure of the prescription data was not necessary to ensure that statements actually made in the Prospectus were not misleading. Under those circumstances, there is no textual or policy basis for imposing liability under Section 11 for the omission — even if the facts in question could be deemed material.

Finally, the imposition of sanctions does not provide a basis for review by this Court. Petitioners' argument that they were improperly sanctioned is based entirely on their claim that the courts below improperly imposed a heightened pleading burden on them. That argument fails not only because the lower courts did not in fact impose a heightened pleading burden on petitioners but also because the district court did not sanction them for failing to meet their pleading burden. Rather, the sanctions order was based on the court's conclusion that the information petitioners gathered in the course of their pre-filing investigation demonstrated that their claims were "objectively frivolous." Whether that conclusion was an abuse of discretion is a fact-intensive determination that has already been thoroughly vetted by the court of appeals and does not merit this Court's attention.

I. This Case Does Not Raise The First Question Presented By The Petition Because The Lower Courts Did Not Apply A "Fact Pleading" Standard To Petitioners' 1933 Act Claims.

Petitioners are right that there are differences among the circuits on the question of whether the heightened pleading requirements of Rule 9(b) apply to claims brought under the 1933 Act when those claims "sound in fraud." But those differences are irrelevant to this case because the Eleventh

Circuit did not purport to decide whether a heightened pleading standard should ever be applied to a 1933 Act claim. Indeed, the Eleventh Circuit had no occasion to decide that issue because it concluded that the complaint failed to state a claim even under the more relaxed pleading standards of Rule 8.[5]

Despite the fact that the Eleventh Circuit did not purport to be applying a heightened pleading standard, petitioners contend that it in fact did so. In support of that argument, petitioners cite passages from the opinions below in which the courts stated that petitioners had failed to offer any factual basis for their conclusory assertions of falsity. But those passages do not suggest that the courts were departing from the requirements of Rule 8.

Although the "demands on the pleader [under Rule 8] are minimal," they "are not tantamount to nonexistent requirements." *Cooperman v. Individual, Inc.*, 171 F.3d 43, 47 (1st Cir. 1999). It is well-settled that even under Rule 8 a court ruling on a motion to dismiss should ignore conclusory allegations, unwarranted inferences, claims that are internally inconsistent, and allegations that mischaracterize or conflict with documents cited or relied upon in the complaint. *See, e.g., South Florida Water Management Dist. v. Montalvo*, 84 F.3d 402, 408 n.10 (11th Cir. 1996) ("conclusory allegations and unwarranted deductions of fact are not admitted as true in a motion to dismiss"); *In re Stac Elecs. Sec. Litig.*, 89 F.3d 1399, 1403 (9th Cir. 1996) ("conclusory allegations of law and unwarranted inferences are insufficient to defeat a motion to dismiss for failure to state a claim"); *Shaw v. Digital Equipment*

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[5] Defendants argued that plaintiffs' claims sounded in fraud – particularly their claim that Kos had "rigged" its clinical trials – and that Rule 9(b) should therefore be applied in judging the adequacy of their allegations. But the lower courts found it unnecessary to reach that issue.

Corp., 82 F.3d 1194, 1216 (1st Cir. 1996) (in "deciding a motion to dismiss under Rule 12(b)(6), a court must take all well-pleaded facts as true, but it need not credit a complaint's 'bald assertions' or legal conclusions").

The lower courts properly applied these unremarkable pleading rules to the particular facts of this case. Petitioners' own allegations demonstrated that their conclusion that the Prospectus misrepresented Niaspan®'s ability to increase "good" cholesterol was an "unwarranted inference" drawn from only partial information. As noted above, petitioners themselves explained that their claim that the 32% figure was false was based entirely on the fact that lower figures had appeared in an earlier press release and article. But the Prospectus itself and other documents that the court could properly consider on a motion to dismiss showed that those earlier statements were based on a smaller number of clinical studies than the information in the Prospectus. Thus, the discrepancy petitioners relied upon was easily explained and cannot provide a basis for claiming that the results set forth in the Prospectus were misrepresented.

The same analysis applies to the other falsity argument petitioners continue to press in this Court. In their complaint, petitioners alleged that Niaspan® would never be commercially viable because only a "tiny fraction" of the population could tolerate its side effects at the 2000 mg dose level required for efficacy. This wholly unsupported assertion, however, was directly contradicted by the clinical studies reported in the Prospectus showing that 2000 mg doses were well tolerated. In order to support their assertion of falsity, petitioners alleged that the clinical studies had been "rigged." But in arguing the motion to dismiss, petitioners were never able to explain *how* they were supposedly "rigged." Indeed, at oral argument on the motion, plaintiffs' counsel essentially admitted that this assertion was a shot in the dark. In light of that admission, the

district court was clearly not required to credit plaintiffs' conclusory allegations of misconduct in ruling on the motion to dismiss.

In their petition, petitioners advance a theory they first raised in response to defendants' motion for sanctions — that the test results on tolerability were skewed because pre-menopausal women were left out of the study. Even assuming that the studies included only men and post-menopausal women, however, that would not support the conclusory assertions in the complaint. Plaintiffs alleged that only a "tiny fraction" of the population could tolerate a 2000 mg dose of Niaspan® (Pet. App. 46) — a description that hardly fits the entire male population and the portion of the female population that is most likely to take a cholesterol-lowering medication.

In any event, whether or not the lower courts properly evaluated the allegations of the complaint under the well-established standards of Rule 8 is clearly not an issue warranting this Court's review.

II. The Eleventh Circuit's Conclusion That There Was No Duty To Disclose Prescription Data Does Not Create A Conflict.

Section 11 does not purport to create a duty to disclose all material information. Instead, it requires disclosure of material information that is "required to be stated" in the registration statement or that is "necessary to make the statements" that are actually made in the registration statement "not misleading."[6] In this case, the Eleventh Circuit carefully considered and rejected petitioners' argument (raised for the first time in their

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[6] By contrast, Section 12 — like Section 10(b) of the 1934 Act — imposes an obligation only to disclose material information that is necessary to make whatever was actually said not misleading.

reply brief on appeal) that Item 303 of SEC Regulation S-K required disclosure of whatever prescription data could have been obtained by the time the Registration Statement became effective. Pet. App. 12-15. The Court also rejected the argument that disclosure of the prescription data was necessary so that statements made in the Prospectus would not be misleading. *Id.* at 16. Petitioners do not challenge either conclusion.

Instead, petitioners argue that Section 11 imposes strict liability on an issuer and negligence liability on underwriters if they fail to disclose information that a court later finds to be material — even if no SEC regulation required it to be disclosed and even if it is not necessary to ensure that statements made in the registration statement are not misleading.

Petitioners contend that a footnote in the Second Circuit's decision in *Kronfeld v. Trans World Airlines, Inc.*, 832 F.2d 726, 730 n.8 (2d Cir. 1987), supports their position and that the Eleventh Circuit's decision in this case creates a split in the circuits. As the Second Circuit specifically recognized in *Kronfeld*, however, that case did not involve the "pure question of a duty to disclose" presented by this case. *Id.* at 732. Instead, the issue in *Kronfeld* was whether the prospectus "omitted to state material facts necessary to make the statements therein not misleading." *Id.* at 735. Under these circumstances, whatever the Second Circuit may have said in a footnote about the breadth of disclosure obligations under Section 11 was clearly dicta.

Furthermore, since *Kronfeld*, the lower courts — including district courts in the Second Circuit — have consistently agreed with the approach the Eleventh Circuit took in this case. *See, e.g., Cooperman v. Individual, Inc.*, 171 F.3d at 49 (there is "no absolute duty to disclose all material information" in a prospectus); *In re Sofamor Danek Group, Inc.*, 123 F.3d 394, 400 (6th Cir. 1997) ("Materiality alone is not sufficient to place

a company under a duty of disclosure"); *Milman v. Box Hill Sys. Corp.*, 72 F. Supp. 2d 220, 227 (S.D.N.Y. 1999) ("to maintain a claim for failure to disclose information pursuant to § 11, a plaintiff must demonstrate both that the defendant had an affirmative duty to disclose the information and that the information was material").

Recently, in *In re Merrill Lynch & Co. Research Reports Sec. Litig.*, 2003 U.S. Dist. LEXIS 11113, at *10-12 (S.D.N.Y. July 2, 2003), the court followed the Eleventh Circuit's decision in this case, citing it (and a number of cases decided in the Southern District of New York) for the proposition that "[t]o state a claim under Sections 11 and 12(a)(2) [based on an omission], a plaintiff must allege that the defendants had a legal obligation to disclose the allegedly omitted information" — that is, plaintiffs must point to an "SEC regulation or other legal authority" that would require the disclosure of the information in question. *Accord Shaw v. Digital Equipment Corp.*, 82 F.3d at 1204 ("The information 'required to be stated' in a registration statement is spelled out both in Schedule A to Section 7(a) of the Securities Act, 15 U.S.C. §§ 77g(a), 77aa, and in various regulations promulgated by the SEC pursuant to its statutory authority").

Thus, there is no conflict or confusion among the lower courts with respect to the proper interpretation of Section 11 that requires this Court's intervention. Nor does the Eleventh Circuit's interpretation raise any important issues concerning the language or policies behind Section 11.

The Eleventh Circuit's interpretation of Section 11 is entirely consistent with its plain language. Section 11 does not impose liability for a failure to disclose "all material facts"; rather, it imposes liability for a failure to disclose "material fact[s] required to be stated" in a registration statement. As the Eleventh Circuit recognized, the interpretation petitioners urge

would render the phrase "required to be stated" completely superfluous. Pet. App. 11.

Furthermore, contrary to petitioners' argument, there is no policy reason for imposing Section 11 liability on issuers and underwriters for failure to disclose "material" information that SEC regulations do not require them to disclose. Materiality often lies in the eye of the beholder. And what appears to be material in the clear light of hindsight may not seem to be material at all at the time a prospectus is drafted. Imposing strict liability on issuers and negligence liability on underwriters under Section 11 for failing to disclose any information that a jury might later determine to be material would inevitably chill investment activity. As the Eleventh Circuit recognized, it would also force issuers and underwriters into a position where they would have no choice but to inundate investors with mountains of minutiae in each prospectus lest they later be accused of omitting some scrap of information that a disappointed investor claimed was material. Pet. App. 12 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 231 (1988), for the proposition that the securities laws should not be interpreted in ways that force issuers to bury investors in "an avalanche of trivial information").

III. The Imposition of Sanctions Does Not Raise Any Issue Warranting This Court's Review.

Petitioners contend that the district court sanctioned them for failing to meet a heightened pleading burden that was improperly applied to their 1933 Act claims. As demonstrated above, however, the courts below did not impose a heightened pleading burden on petitioners. Moreover, the district court did not sanction petitioners for their failure to meet the applicable pleading standards. Instead, it sanctioned them because their own arguments made it abundantly clear that they had filed their complaint without any factual basis for believing that

investors had been misled — precisely the kind of conduct Congress intended to curb when it enacted the PSLRA.

In any event, whether the district court abused its discretion in concluding that all but one of petitioners' claims were "objectively frivolous" is a fact-specific issue that plainly does not warrant this Court's review.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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